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The Trade and Economic Benefits of Enhanced Intellectual Property Protection for Pharmaceuticals in Canada

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Introduction: The Trade and Economic Benefits of Enhanced Intellectual Property Protection for Pharmaceuticals in Canada

Nadeem Esmail

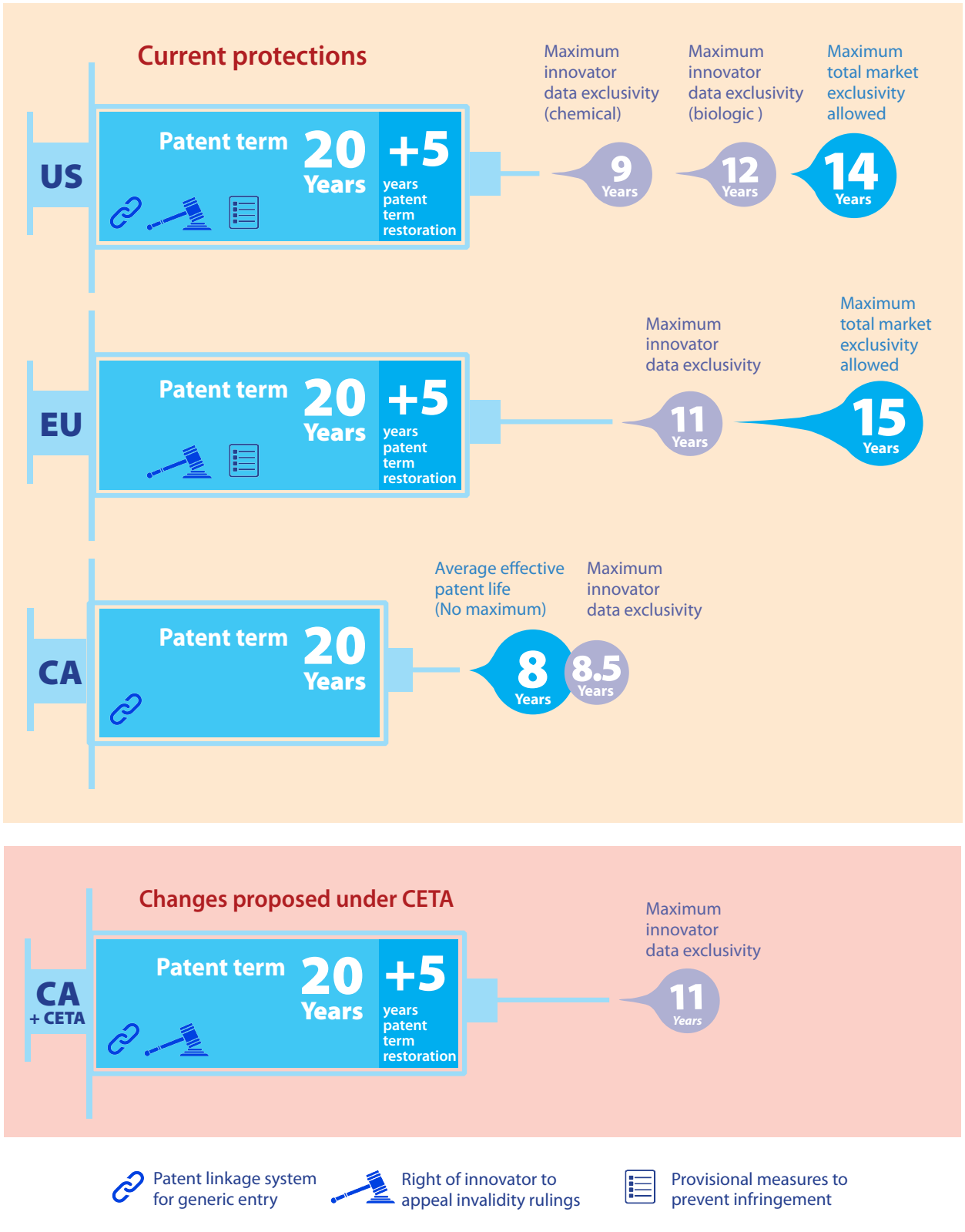
Canada is in the midst of a number of free trade negotiations, the most important of which are the soon-to-be completed Comprehensive Economic and Trade Agreement (CETA) with the European Union and the multi-country Trans-Pacific Partnership (TPP). A key issue to be settled in these negotiations is intellectual property (IP) protection for pharmaceutical innovation. In negotiations for both agreements, Canada faces pressure to enhance IP protection so that it more closely aligns with protection that prevails in Europe and the United States, among other nations. While enhanced IP protection is not the only matter to be resolved in these negotiations, and while other criteria need to be met before Canadians can reap the benefits of these free trade agreements, this policy area is nevertheless of significant importance to Canada's counterparts in these trade discussions.

The pressure for Canada to enhance IP protection comes on three key fronts. The first is patent term restoration (that is, restoring patent time lost to mandatory regulatory delays). The second is on a right of appeal for patent holders (in other words, allowing patent holders in Canada the right to appeal court rulings that invalidate their patent). And the third is extended data exclusivity, the time during which generic manufacturers are not permitted to use innovator data for drug approvals.

A central question for Canada in these negotiations is whether the increased cost of medicines that would result from enhanced IP protection are outweighed by potential economic benefits, such as additional economic activity in the innovative pharmaceutical sector in Canada and those generated by free trade agreements. The two essays in this series seek to answer that question by examining

Intellectual Property Protection for New Drugs

Comparing Canada to the United States and the European Union



potential gains from trade as well as additional economic benefits that would result from stronger intellectual property protection in Canada.

What Canada stands to gain

In "Strengthening Intellectual Property Protection for Pharmaceutical Innovation: What Canada Stands to Gain," pharmaceutical IP protection expert and associate professor of economics at Colorado College Dr. Kristina Lybecker finds Canada's protection of pharmaceutical innovator intellectual property falls short of international standards. Pharmaceutical innovators face shorter effective periods of patent protection in Canada, fewer years of data exclusivity, and an unequal court appeal process for challenged patents relative to the property protection provided under regulations in other developed countries. These shortcomings of the Canadian IP protection regime reduce drug costs, but come at a price to Canada's economy and its access to innovation.

After reviewing the evidence, Dr. Lybecker finds the benefits of enhanced IP protection would be many and multifaceted. Broader trade benefits include reduced tariffs and trade barriers, greater access to foreign markets, and potentially increased trade. Further benefits include reduced legal ambiguity and litigation in Canada, greater research and development (R&D) expenditures, additional job creation in the pharmaceutical industry, greater pharmaceutical self-sufficiency, improved access to medical innovations, and additional innovation in medicines. In all, Dr. Lybecker finds the trade and economic benefits of enhanced IP protection would more than compensate for the estimated $367 million to $903 million per year increase in pharmaceutical expenditures. Indeed, estimates of increased trade through CETA alone suggest a $12 billion annual benefit to the Canadian economy.

The benefits from trade agreements

In her essay "Canada's Trade Agreements and the Pharmaceutical Industry: The Road to Asia Runs through Brussels," Dr. Laura Dawson, international trade specialist and former senior advisor to the US government on trade and economic issues, adds to the case for enhanced IP protection in an examination of the potential economic benefits of CETA and the TPP. Dr. Dawson finds considerable economic benefits from both trade agreements that may justify Canadian concessions in this policy area.

Dr. Dawson's essay reveals that CETA offers access to the world's largest single market (the EU) with a population of over 500 million, and a GDP of $17.4 trillion. According to a joint study by the Canadian and EU governments, CETA has been estimated to offer a 20 percent boost to Canada's exports to the EU. More specifically, CETA offers reduced tariffs (particularly for fish and seafood, foot-

wear, and textiles), access to the EU's $3 trillion government procurement market, and some $2.3 billion in non-tariff barrier reductions (including regulatory duplication, packaging, and labeling requirements).

The Trans-Pacific Partnership offers a similarly large economic benefit, where TPP countries (Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the US, and Vietnam) represent a prospective free trade zone of over 785 million people with a GDP in excess of $26.4 trillion. TPP may yield annual income gains of $9.9 billion for Canada and increase exports by nearly $16 billion. While the short term gains for Canada are relatively small, the major attraction of this trade agreement is the size and dynamism of the Asian market (including China's potential future inclusion) where high growth rates suggest promising future demand for consumer and luxury goods. Canada also maintains defensive interests in TPP negotiations; in particular its economic and political relationship with the United States and in ensuring it is not shut out of preferential market access arrangements in Asia and Latin America.

A strong and clear positive policy direction for Canada emerges from the two essays. Of course, no policy position is without its costs, which in this case have been a strong motivator for many policy analysts and commentators opposed to enhanced IP protection. As Dr. Lybecker notes, "[t]he debate over intellectual property rights in the pharmaceutical industry elicits passionate arguments from both defenders and opponents. On both sides of the issue, advocates cling to emotional justifications and vehemently defend their positions." When it comes to CETA and TPP negotiations, however, the benefits of trade (including greater access to markets with a combined GDP in excess of $43.8 trillion and annual estimated benefits of nearly $22 billion for Canada) far exceed any increase in health expenditures that might result from bringing Canada's IP protection regime in line with those in other developed nations. Further offsetting the increase in drug costs is a potential expansion in Canadian economic activity, as well as an increase in drug research and innovation, and access for Canadians to that innovation.

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Strengthening Intellectual Property Protection for Pharmaceutical Innovation: What Canada Stands to Gain

by Kristina M. Lybecker[1]

Summary

Canada is currently in the midst of negotiating two international trade agreements: the Comprehensive Economic and Trade Agreement (CETA) with the European Union, and the Trans-Pacific Partnership Agreement (TPP) with Australia, Brunei Darussalam, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam.

Critics have argued that Canada's protection of intellectual property in the pharmaceutical industry falls short of international standards. Historically, international trade agreements have been used repeatedly as the impetus for strengthening intellectual property rights. Strong precedents were set with Canada's accession to the North American Free Trade Agreement (NAFTA) in 1992, and with the Marrakesh Agreement which established the World Trade Organization (WTO) in 1995.

The current CETA and TPP trade negotiations necessitate that the legal framework surrounding intellectual property rights in the pharmaceutical industry be re-examined. There are three specific changes under discussion: data exclusivity, patent term extensions, and the Innovator's Right of Appeal.

The benefits to international trade agreements and the requisite stronger intellectual property rights for the innovative pharmaceutical industry are many and multifaceted. Most fundamentally, enhanced intellectual property protection will strengthen the innovative pharmaceutical industry and facilitate Canada's accession to the international trade agreements under negotiation. From a wider perspective, the benefits to Canada from intellectual property protection will

1 The author wishes to thank Steven Globerman and other anonymous reviewers for their thorough review of this manuscript. All remaining errors are the author's own.

include increased trade, greater access to foreign markets, and reduced tariffs and trade barriers. There are other, less obvious benefits, too. They include reduced legal ambiguity and litigation, greater research and development expenditures, additional job creation in the pharmaceutical industry, greater pharmaceutical self-sufficiency, improved access to medical innovations, and additional innovation in cutting-edge treatments and therapies.

At first glance, the advantages of stronger intellectual property protection for the innovative pharmaceutical industry are impressive. Closer scrutiny reveals them to be essential to continued economic growth and prosperity.

Introduction

Canada is currently in the midst of negotiating two international trade agreements: the Comprehensive Economic and Trade Agreement (CETA) with the European Union, and the Trans-Pacific Partnership Agreement (TPP) with Australia, Brunei Darussalam, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. These negotiations have led to a careful examination of Canada's intellectual property (IP) protection regime, particularly the protection available to the innovative pharmaceutical industry. Critics, including the European Union and the brand-name industry, argue that Canada's protection of intellectual property in the pharmaceutical industry falls short of international standards, and both agreements may require that to be completed, these protections be strengthened.

The debate over intellectual property rights in the pharmaceutical industry elicits passionate arguments from both the industry's defenders and opponents. On both sides of the issue, advocates cling to emotional justifications and vehemently defend their positions. Public policymaking surrounding access to medicines is located at the intersection of economic policy and public health. The stakes are very high, not only for industry profits, but for human life. Accordingly, it is not surprising that for the pharmaceutical industry intellectual property rights (IPRs) have become extremely contentious in the ongoing negotiations.

Without question, the legal architecture surrounding intellectual property rights protection and the national regulatory regime are powerful forces shaping the pharmaceutical industry, its profitability, productivity, and innovative future. Each of these forces also has consequences for the Canadian economy and for access by Canadians to medical innovations. In the course of ongoing trade negotiations, several aspects of the Canadian system have come under scrutiny and changes to these aspects have become central to the negotiations.[2]

2 Of course it is impossible to discern precisely how important this aspect of the trade agreement negotiation is relative to all others, as the negotiations are ongoing and many aspects under discussion are confidential. It is clear, though, that IP protection is very important for the pharmaceutical industry and has the potential to become a sticking point in these negotiations.

The legal and economic issues permeating the pharmaceutical industry are distinct from those in other research-intensive industries due to several interrelated features. As Danzon (1999) describes, there are three features in particular: the rapid pace of technological change and the vital importance of intellectual property protection; the regulation of virtually every aspect of the industry; and the global nature of pharmaceutical research and development along with the incentive for free-riding on the global joint costs of development. Each of these features presents unique economic and legal challenges to the innovation of new drugs and to the public health policies that surround their production, marketing, and distribution.

Given that patents and other forms of intellectual property protection are disproportionally important to the research-based pharmaceutical industry, the legal architecture necessary to foster a robust, innovation-based industry is extensive. This paper aims to assess the proposed changes to the Canadian legal regime and evaluate the impact and benefits of stronger intellectual property protection for the innovative pharmaceutical industry— adjustments that will certainly encourage industry growth.

Admittedly, these changes are not costless. An internal Canadian government calculation of the effect of stiffer brand-name patent protection places the cost for the extra rigour at between $367 million and $903 million per year, since generic substitutes would be slower to market (Scoffield, 2012). The changes would result in provincial governments and consumers purchasing more expensive, brand-name drugs for a longer period. However, the costs of extended patent protection must be weighed against its benefits, and the benefits are significant. Stronger intellectual property protection for pharmaceuticals enhances innovation, which generates both economic and health benefits. This study examines these benefits in the context of international trade benefits, industry prosperity and investment, domestic economic growth, and health consequences.

The use of trade agreements to strengthen intellectual property rights

Historically, international trade agreements have been used repeatedly as the impetus for strengthening intellectual property rights. Not surprisingly, pharmaceutical patents are again at the forefront of the Comprehensive Economic and Trade Agreement (CETA) and the Trans-Pacific Partnership Agreement (TPP) negotiations. Joel Lexchin argues that "there has been an almost inseparable link between the pharmaceutical industry, patent protection, and trade agreements" (Lexchin, 2001: 1). Strong precedents were set when the Canada-US Free Trade Agreement was signed in 1987, followed by Canada's accession to the North American Free Trade Agreement (NAFTA) in 1992, and again with the Marrakesh Agreement that established the World Trade Organization (WTO) in 1995. In order to comply

with NAFTA's provisions, Canada's federal government introduced the Patented Medicine Notice of Compliance Linkage Regulations (PC(NOC)) in 1993. These regulations tie the regulatory approval of generic medicines to the patent status of the innovative brand-name product. In essence they seek to balance the timely entry of generic versions and the patent rights of innovator firms.

Table 1 describes three major trade agreements and the resulting changes to Canadian Patent Law, beginning with the Free Trade Agreement (FTA) between Canada and the United States. Despite the regulatory changes stemming from these agreements, Europe, the research-based pharmaceutical industry and many within Canada's business community argue that Canada's patent regime remains below international standards. Accordingly, the debate surrounding the regulations has taken on increased importance in the negotiation of current trade agreements. While earlier trade agreements certainly addressed pharmaceutical patent protection, the pending international trade agreements have the potential to again alter extent of protection.

Table 1: Trade Agreements and Changes to Canadian Patent Law

Trade Agreement	Date entered into force	Parties	Accompanying change in Canadian patent law	Date law took effect	Main features
Free Trade Agreement (FTA)	1987	Canada and United States	Bill C-22	1987	New drugs exempt from compulsory licensing for 7 years; exemption extended to 10 years if active ingredient manufactured in Canada
North American Free Trade Agreement (NAFTA)	1994	Canada and United States and Mexico	Bill C-91	1993	Compulsory licensing abolished (retroactive to December 1991); patent life changed from 17 years from date patent granted to 20 years from date patent filed for (retroactive to October 1, 1989)
Trade Related Aspects of Intellectual Property Rights (TRIPS)*	1995	Worldwide			

*TRIPS was part of the package that created the World Trade Organization (WTO).
Source: Lexchin, 2001: 2.

Proposed changes to Canada's legal architecture

In the agreements currently under negotiation, CETA would, and TPP may, require some changes in Canada's legal architecture, ensuring more effective intellectual property protection for the innovative pharmaceutical industry. Given the vital importance of patents and other forms of intellectual property protection to this industry, strong legal protection is key to the development and growth of a robust innovation-based pharmaceutical industry.

Current trade negotiations necessitate that the legal framework surrounding intellectual property rights in the pharmaceutical industry be re-examined. Table 2 compares pharmaceutical IP regimes across Canada, the European Union, the United States, and other countries. This should provide some context for the Euro-

Table 2: Comparison of Canadian and non-Canadian Pharmaceutical IP Regimes

	Canada	European Union (27 Member States)	United States	
Right of Appeal	PM (NOC) regulations that link market approval to patent validity. No provisional measures available. Inequities in "linkage regime" (e.g., no effective right of appeal for innovators) favour generic manufactures over innovators.	No "linkage" regimes like in Canada or US. However, provisional measures (e.g., interlocutory relief) also available in EU to prevent patent infringement.	Linkage regime similar to Canada's (the "Hatch-Waxman" system) Absence of problematic inequities: e.g., innovators have an effective right of appeal. Provisional measures available.	
Data Exclusivity	8 years exclusivity No extension for new indications	10 years exclusivity + 1 year extension for new indications	5 years exclusivity + FDA approval time (1+ years) + 3 year extension for new indications	12 years exclusivity for biologics
Patent Term Restoration	None	Maximum 5 years additional market exclusivity through Supplementary Protection Certificate (SPC). Maximum combined patent/SPC post-approval market exclusivity of 15 years.	Maximum 5 years additional market exclusivity. Maximum combined post-approval market exclusivity of 14 years.	

Source: Rx&D, reproduced in CIPC, 2011: 12.

pean demands required for the completion of the CETA. Specifically, the three changes under discussion include: the innovator's right of appeal, data exclusivity, and patent term extensions.

Innovator's right of appeal

The first area in which Canadian law differs significantly from that of the United States and the European Union is the right of appeals. As described by the Intellectual Property Institute of Canada, the Canadian process proceeds as follows:

> In principle, either the generic or the patentee may [challenge] an adverse holding in PM(NOC) [Patented Medicines (Notice of Compliance) Regulations] proceedings to the Federal Court of Appeal. However, if the generic is successful, the Minister of Health will normally issue the NOC almost immediately. Once the NOC has been issued, the Federal Court of Appeal will refuse to hear the appeal on the basis that it is moot. The patentee's recourse is to bring an infringement action against the generic, from which there is a right of appeal. (IPIC, 2012: 21)

In essence, innovator companies are denied an effective right to appeal the NOC decision prior to market access for the generic product, while the generic company would have the right to appeal if the court rules in favour of the innovator company. Given that the treatment of innovator and generic companies differ, the system is inherently inequitable and discriminatory. In a May 2010 press release, Sanofi-aventis Canada summed up the problems faced by the research-based industry: "Canadian innovative pharmaceutical companies have no effective right of appeal when facing intellectual property challenges. This lack of government policy leadership is leading to genericization of branded medicines even while they are still under patent protection. This threatens the company's ability to maintain its R&D investments, capital expenditures and job creation opportunities" (CIPC 2011: 14). This inequity also creates a climate of uncertainty and litigiousness, where innovators cannot know if or when the courts will dismiss their patents, without the opportunity for direct appeal.

The proposal for an innovator's right of appeal would ensure that patent holders and generic manufacturers would be treated in a balanced and equitable way with respect to the validity of a patent. This would allow for an effective right of appeal by an innovator following an adverse decision in an NOC proceeding in the federal court (IPIC, 2012: 21).

Data exclusivity

In part, innovative drugs (particularly small-molecule pharmaceuticals) are shielded from generic competition in Canada through the protection of innovator

data (resulting from clinical trials) for eight to eight-and-a-half years, though drugs must meet certain criteria to be eligible. Specifically, data exclusivity does not apply to new applications for existing drugs. The maximum term of data protection is eight-and-a-half years: no abbreviated submission (the submission for approval of a generic version of the drug) is permitted for six years, no regulatory approval of abbreviated submissions will be given for an additional two years, and an additional six months will be added for submissions that include paediatric studies. Grootendorst and Hollis (2011) note that the European Union's regime, under Directive 2004/27/EC, provides for data exclusivity and extensions of 8+2+1 years. Specifically, this time is broken down as: no abbreviated submission is permitted for eight years, no regulatory approval for that abbreviated submission will be granted for an additional two years, and an additional year of data exclusivity can be added for significant changes (new indications). In addition, in the European Union, organizations (known as sponsors) applying for approval are required to conduct paediatric studies, where applicable. At the same time, the United States provides for five years of data exclusivity with eligibility for an additional three years for exclusivity limited to new indications and essential clinical trials. Beyond this, the United States provides 12 years of data exclusivity for new biologics. Currently, Canada considers that no specific unique legislation is necessary to provide a regulatory framework for biologics, though Health Canada published a guidance document in March of 2010.

Clinical trials ensure that drugs are safe and effective, but they command a great cost, resulting from years of effort and millions of dollars in expenses. Torstensson and Pugatch note that clinical trials may now account for up to 60 percent of the total cost of drug research and development. For a period of time, these data are protected from use by generic companies that use the clinical trial data to demonstrate their products are "bioequivalent," an essential step in the approval process for generic drugs. Before the implementation of NAFTA and TRIPS, pharmaceutical clinical trial data were treated as trade secrets in the United States and the European Union, but not in Canada. The ratification of these trade agreements resulted in more uniform international rules. However, as noted above, the length and extent of protection in Canada lags behind that of other countries.

In the context of the CETA negotiations, Europe proposes an increase in data exclusivity in Canada to ten years with a maximum of 11 years. The additional year of data protection would be provided in cases of new indications. In addition, Canada is being encouraged to adopt language that provides for more expansive data exclusivity protection, such that new uses, not just "innovative drugs," are eligible for protection. Beyond extended data protection for small-molecule drugs, Canada is being asked to adopt specific protection for biologics.

The justification for enhanced data exclusivity laws rests in the incentives provided to research-based firms to produce the data required for regulatory approval. While data exclusivity regimes do differ across countries in the

nature, scope, and extent of protection, stronger regimes clearly enhance the incentive to innovate. "The pharmaceutical and agrochemical industries have often successfully argued that if regulators allow an equivalent product (a "generic") to go to market on the strength of the test data provided by the originator company, there would be no incentive for anyone to produce the test data necessary to obtain market approval" (Krattinger et al., 2007). The proposed changes would both bring Canadian law into line with international standards and encourage innovation.[3]

Patent term extension

As table 2 describes, Canada fails to provide an extra period of patent protection as compensation for time lost to mandatory governmental regulatory approval delays. The United States and European Union, like most other nations, restore a period of patent protection to innovators to make up for the lengthy process of drug approvals. Although Canadian law provides for a 20-year patent terms, as required by the WTO's TRIPS Agreement, Canada lacks a provision for the reduction in effective patent life due to the lapse between the filing of a patent and the grant of market authorization.

The United States' 1984 Patent Term Restoration and Competition Act provides innovators one patent extension per product. In addition, the innovator company has the discretion to determine on which patent the extension is sought. The maximum extension allowed is five years, but the total remaining patent term from the date of marketing approval cannot exceed 14 years. Specifically, the extension is calculated as 50 percent of the period of clinical trials in addition to the full regulatory review period.

Patent protection is disproportionally more important in the pharmaceutical and chemical industries than in most other sectors to ensure that the researcher appropriates the returns to R&D.[4] Canada is currently the only country among the

3 Given that generic firms rarely undertake clinical trials or search for new indications, the spillover benefits of reduced data exclusivity/earlier access to data are likely very limited in this area.

4 Building on the 1987 *Yale Survey* (Levin, Klevorick, Nelson, and Winter, 1987), Cohen et al. reexamine the effectiveness of various means of appropriating intellectual property. Echoing the earlier findings, the 1994 *Carnegie-Mellon Survey* finds that there are tremendous differences in the effectiveness of various appropriability mechanisms, both among industries as well as within them. Overall, while patents are again seen as "unambiguously the least effective of the appropriability mechanisms," the drug industry regards them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996: 14). This is confirmed by the industry's high propensity to patent both product innovations (overall highest propensity at 99%) and process innovations (fourth highest propensity at 43%) (Cohen, Nelson, and Walsh, 1996: 21-22). Several other studies report that the protection of intellectual property is disproportionally more important to the chemical and pharmaceutical industries. These include: Levin, Klevorick, Nelson, and Winter (1987); Taylor and Silberston (1973); Scherer (1997); Mansfield (1986); Mansfield, Schwartz, and Wagner (1981); and Tocker (1988). These

G8[5] nations that does not offer any form of patent extension (IPIC, 2012: 18). Europe proposes legislation granting a potential patent term extension (five years plus an additional six months if paediatric studies have been completed) to innovator firms in order to recoup the time spent attaining mandatory governmental regulatory and marketing approval. The restoration of five years of patent life, as is the practice in other jurisdictions, would lengthen the effective patent term of innovative therapies, enhancing the incentives to invest in the research and development costs necessitated by these treatments.

In sum, proponents of stronger intellectual property rights protection advocate three changes to the Canadian IP regime. First, they believe that Canada should enhance and extend the data protection regulations to provide 10 years of protection and include new indications (for an additional year of protection). In addition, innovative pharmaceutical firms should be eligible for patent term extensions in order to recover time lost to regulatory and marketing approvals. Finally, the adoption of the innovator's right of appeal would level the playing field, allowing both innovator and generic firms the right of appeal if the court rules against them. These changes would bring the Canadian regime in line with international standards. They would also signal that Canada embraces innovation and supports knowledge-based industries.

The impact and benefits of international trade agreements and stronger intellectual property rights for the pharmaceutical industry

Strengthening the industry and boosting trade

The benefits to international trade agreements and the requisite stronger intellectual property rights for the innovative pharmaceutical are many and multifaceted. Most fundamentally, enhanced intellectual property protection will strengthen the innovative pharmaceutical industry and facilitate Canada's accession to the international trade agreements under negotiation. From a wider perspective, the benefits will include increased trade, greater access to foreign markets, and reduced tariffs and trade barriers. Benefits will also include reduced legal ambiguity and litigation, greater research and development expenditures, additional job creation in the pharmaceutical industry, greater pharmaceutical self-sufficiency, faster launch times for new medicines, and additional innovation on cutting-edge treatments and therapies.

studies are echoed by arguments from within the pharmaceutical industry: Mossinghoff (1998); Peretz (1983); Mossinghoff (1987); Santoro (1995); Smith (1990a, 1990b); Mossinghoff and Bombelles (1996); and PhRMA (1997).

5 The G8 or "Group of Eight" consists of the world\rquote s eight largest economic powers. These include Canada, France, Germany, Italy, Japan, Russia, the United Kingdom, and the United States.

Table 3: Economic Performance per Employee
15 IP-Intensive versus 12 Non-IP-Intensive Industries, 2000-2007 (in US$)

	Wages	Sales	Value-Added	Exports	R&D Spending	Capital Spending
IP-Intensive	$59,041	$485,678	$218,373	$91,607	$27,839	$15,078
Non-IP-Intensive	$37,202	$235,438	$115,239	$27,369	$2,164	$6,831
Difference	$21,839	$250,240	$103,134	$64,238	$25,676	$8,246
(Multiple)	1.6	2.1	1.9	3.4	12.9	2.2

Source: Pham, 2010: 4.

The benefits to trade openness are extensively documented by economists (see, for example, IMF, 1997; Srinivasan and Bhagwati, 1999; Frankel and Romer, 1999; and IMF, 2001). Trade agreements, openness, and the elimination of barriers to free trade are associated with higher growth rates, rising standards of living, and expanding industries. For Canada, these international agreements would result in increased trade and greater access to foreign markets. In terms of the CETA alone, estimates are that it would boost bilateral trade with the European Union by 20 percent and add $12 billion annually to the Canadian economy (Scoffield, 2012: 2).

In addition, adopting the proposed changes to Canadian legislation would signal a broader commitment to innovative and IP-intensive industries, making Canada a more attractive market for such industries. Knowledge-based industries are the engines of economic growth and vital to national well-being and global competitiveness. Pham (2010) examines the impact of innovation and the role of intellectual property rights on US productivity, competitiveness, jobs, wages, and exports. His findings are striking and paint a clear picture of the value of IP-intensive industries to economic prosperity. Table 3 illustrates the difference between IP-intensive and non-IP-intensive industries, across a range of metrics.

Creating jobs

As table 3 shows and as Pham further describes, IP-intensive industries sustain greater long-term economic growth, generate trade surpluses, and pay both highly-skilled and low-skilled employees more than non-IP-intensive industries. Overall, Pham's findings confirm the importance of innovation and intellectual property in job creation, higher wages, exports, and sustained economic growth, further emphasizing the need for a hospitable environment for innovation (Pham, 2010: 4-6).

Beyond the more general economic advantages of healthy IP-intensive industries, the innovative pharmaceutical industry generates an additional set of benefits for the economy, both direct and indirect. Figure 1 describes these benefits and the channels through which a strong innovative pharmaceutical sector stimulates the economy.

Of course, Canada is not a populous nation and is largely a net importer of patented medicines. Hence, the gains from stronger IP protection for pharmaceuticals in this country may be substantially smaller than in the US or Europe. However, this is not to say that the benefits are insubstantial.

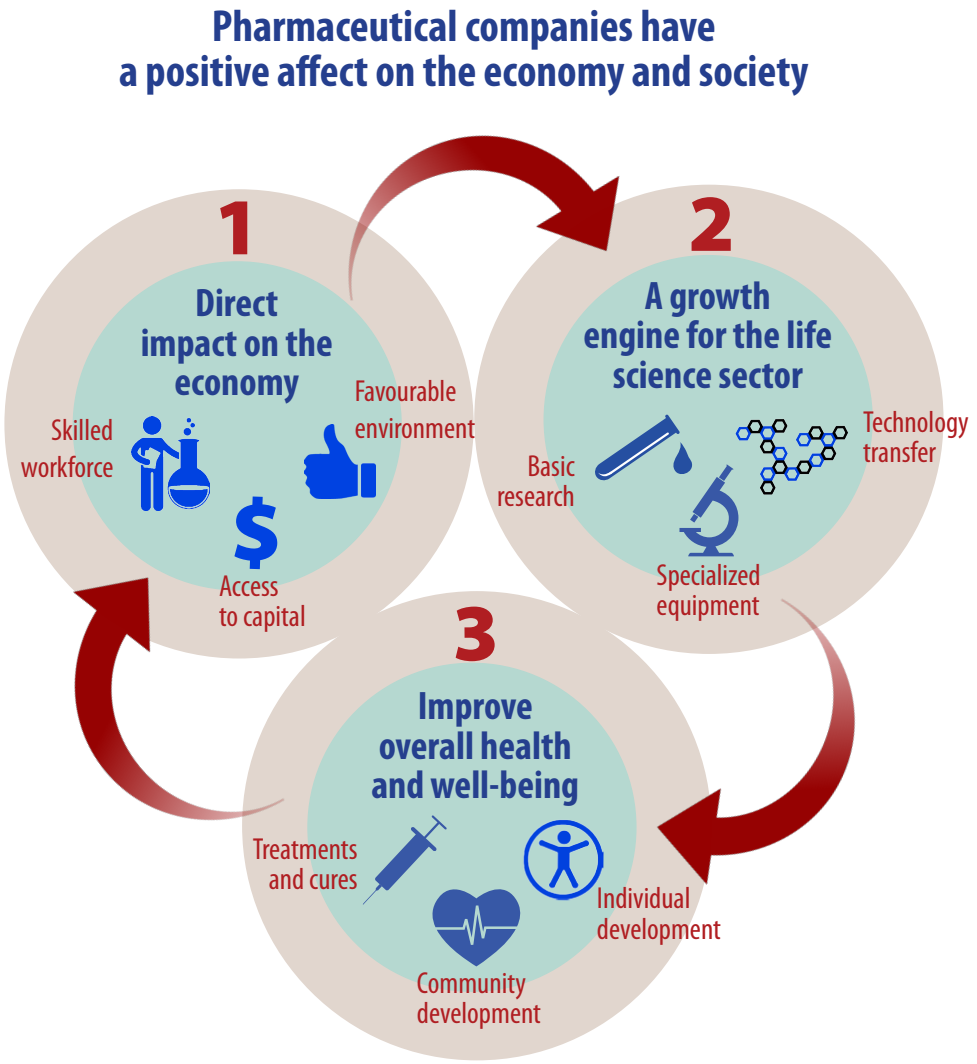
The benefits figure 1 describes translate directly to the Canadian economy. Since the *Patent Act* was amended in 1987, Canada's research-based pharmaceutical companies have reported an increase in employment (full-time employees) by member companies from 14,521 in 1987 to 45,999 in 2011 (Lexchin, 2001: 9 and KPMG, 2012: iv). The research-based pharmaceutical industry currently funds 27 percent of all health science research and development in Canada (CIPC, 2011: 5). Further, R&D spending by Canada's research-based pharmaceutical companies grew from $106 million in 1987 to $1.18 billion in 2011 (CIPC, 2011: 11). These numbers indicate a positive trend. That trend needs to be nurtured and continued with additional protection for IP in the pharmaceutical sector in order to bring Canada's IP regime to a level similar to that found in other nations.

Industry growth

Beyond the existing benefits, there is tremendous potential for growth in this sector. In 2010, sales for the global pharmaceutical industry reached US$733 billion, an increase of 3.6 percent over the previous year (KPMG, 2012: 1). Moreover, industry experts predict growth of 6 percent annually to reach US$981 billion by the end of 2015 (KPMG, 2012: 1). The Canadian market in particular represents two percent of global sales but only one percent of global pharmaceutical investments (CIPC, 2011: 6). A more competitive IP environment would ensure that additional research and development investments are drawn to Canada and the potential for the growth of the Canadian market can be realized.[6] These efforts would ensure an expansion of the existing contribution to the Canadian economy, described in table 4.

6 While government entities do fund medical research, most notably in HIV/AIDS, infectious disease, and oncology, much of this is basic research which is then developed and commercialized by private firms. Further, industry is the principal funder of research in most other areas, and is responsible for approximately 65 percent of US biomedical research (Dorsey et al., 2009; Moses and Martin, 2011).

Figure 1: Economic Benefits of the Pharmaceutical Sector



Source: KPMG (2012), pg.14.

Improving health outcomes

The benefits of a vibrant innovative pharmaceutical industry translate into treatments that enhance and extend life as well.[7] Over the past several decades, new

7 While much of the innovation discussed here was funded by sales in markets other than Canada (often larger markets with higher patented medicine prices), and while Canada may be able to "free ride" on other countries' funding of innovation (in particular the US), it is nevertheless true that stronger IP protection in Canada would add to pharmaceutical R&D at the margin. While it

Table 4: Annual Contribution of the Innovative Pharmaceutical Industry to the Canadian Economy

Types	Contribution (Direct and indirect impacts)
Value added (excluding indirect corporate taxes)	$3 billion
Employment (FTE)	45,999
New Infrastructure (January 2011 – September 2012)	$450 million
R&D (including non-eligible SR&ED)	$1.08 billion

Source: KPMG, 2012: iv.

medicines have increased longevity, accounting for 40 percent of the two-year increase in life expectancy achieved in 52 countries between 1986 and 2000 (Lichtenberg, 2003). Other examples include the treatment of HIV/AIDS and cancer. Since the mid-1990s and the development of a new wave of medicines to treat HIV/AIDS, the US death rate from AIDS dropped about 70 percent (CASCADE Collaboration, 2003). In addition, since 1971 our arsenal of cancer medicines has tripled. These new treatments account for 50 to 60 percent of the increase in six-year cancer survival rates since 1975 (Lichtenberg, 2004). In particular, data shows that in 2003 the total number of people who died of cancer went down for the first time in more than 70 years (Hoyert et al., 2006).

The nurturing of Canada's domestic innovative industry is important for another reason as well. Increased domestic production could help lessen Canada's dependence on imports to supply pharmaceutical needs. This independence is particularly important when pharmaceutical shortages arise, and shortages are becoming increasingly prevalent not just in Canada, but elsewhere, too. In a 2010 report, the Canadian Pharmacists Association recognized that the "globalization of the drug market may be a contributing factor" to Canadian drug shortages (Canadian Pharmacists Association, 2010: 10). As such, greater domestic production may lessen the risk of a shortage. In 1983, imports represented just 18 percent of the domestic market; by 2000, they accounted for 75.5 percent (Lexchin, 2001: 8). Greater domestic production may also lessen supply chain risk, including appropriate regulatory oversight of manufacturing facilities, and shorter transport links reducing risks of adulteration, counterfeit entry, and cargo theft. Greater

cannot be said which drugs in recent years might not have been approved/sold in Canada in the absence of stronger IP protection, it is clear that stronger protection in Canada will increase the potential for R&D investment in the pharmaceutical industry.

self-sufficiency would result from a stronger domestic industry and increased investment in local production.

However, these benefits will only accrue to Canada if the intellectual property protection regime is competitive. A 2010 report by the Conference Board of Canada gives Canada poor marks on innovation: "Despite a decade or so of innovation agendas and prosperity reports, Canada remains near the bottom of its peer group on innovation, ranking 13th among the 16 peer countries. Canada performs poorly on most of the 21 indicators, scoring 13 "D"s, 2 "C"s, 6 "B"s, and no "A"s. The "D" grades underline Canada's relative weakness in all three categories of the innovation process—creation, diffusion, and transformation" (Conference Board of Canada, 2010: 1). The competition for innovation-based industries is global and Canada must step up the extent of protection if it is to successfully attract innovation-based firms. The specifics translate into the changes recommended earlier in this study.

The improvements Canada could make

It is essential to recognize that research-based pharmaceutical companies take on greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be rewarded and the effective patent life should be sufficient to recoup these investments. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). The investment of time is also significantly greater for the innovative pharmaceutical industry. Table 5 highlights the differences in the drug development processes of innovative and generic companies, pointing to the necessity of strong IP protection for a healthy domestic industry. The investments of time, resources, and financial support by innovative companies are far greater than those made by generic firms. Continued investment and innovation depend upon strong intellectual property protection and the ability of innovative firms to recoup their investments.

According to Canadian government calculations, compliance with all EU demands on patent-term restoration would extend brand-name patents by 2.66 years on average, years that are vital to recovering the R&D investment (Scoffield, 2012: 1). While patent life is virtually identical in all countries—20 years from the date of filing—the length of the effective patent life differs across countries. Under Canadian law, drugs usually have a period of market exclusivity ranging from seven to nine years. In the United States and European Union, the effective patent life is lengthened through the restoration of time lost due to regulatory delays, up to five years beyond the 20 years from the filing date (CIPC, 2011: 11). The additional time provided by the proposed patent-term extension would bring Canada in line with international standards, making this market more attractive for the innovative

Table 5: Drug Development Process and Comparisons

Drug Development Phases	Innovative Companies	Generic Companies
Research and Development	2 – 6.5 years (early stage development)	6 months to 1 year (secure active ingredient and formulation)
Tests and Trials	7 years for 60% of total costs	3 to 6 months for $1 million
Time from Laboratory to Market	11 to 13 years	2.25 to 6.5 years
Estimated Total Costs	$897 million	$4 million
Time to Recoup Investments	7 to 9 years	No time limit

Source: Merck website, reproduced in CIPC, 2011: 12.

pharmaceutical industry and the investments and jobs it creates. In addition, there is some evidence to suggest that enhanced intellectual property protection may speed the launch of new therapies and access to new innovations (Wang, Ji, and Lin, 2003: 277).

It is also critical for Canadian legislation to provide for more expansive data exclusivity protection, such that new uses, not just "innovative drugs," are eligible for protection. Such a change in language rewards continued research on existing therapies. Granted, it may be argued that incremental innovations may contribute less to social welfare than innovations that are both first-in-class and best-in-class. However, follow-on innovations are undeniably significant advances and are therefore worth encouraging financially.[8] The Canadian patent regime should reward subsequent innovations and also allow original innovators to capture a share of the returns from incremental innovations that were spurred by the initial technological advance. A 2009 study by the US Congressional Research Service notes that since much technological innovation occurs incrementally, incremental innovations may provide significant benefit to patients and promote competition (Thomas, 2009: ii).

8 The value of incremental innovation is well established. First-in-class medicines are rarely optimal and adaptive innovations allow for expanding therapeutic classes, increasing the number of available dosing options, and discovering new physiological interactions of known medicines. Moreover, treatments developed through incremental innovation have a different molecule, profile, regimen, dosage, speed of action, or metabolism, providing greater choice to doctors who are able to prescribe treatments based on each patient's individual case. This allows for greater personalization of the treatment prescribed for the same illness. Intellectual property rights are essential not only for radical innovation but also for the small steps that improve upon radical innovation. Increased competition within a therapeutic class also creates price reducing competition. Further, it is worth noting that 63 percent of the drugs on the World Health Organization's essential drug list are incremental innovations. For an excellent discussion of the value of incremental innovation, see Wertheimer et al., 2001.

The benefits of improved IP protection in Canada

The establishment in Canada of the innovators' right of appeal would create greater stability and predictability for research-based companies. Under the existing system, tremendous uncertainty surrounds the period of market exclusivity and innovators never know if or when their patents will be dismissed in court. Without the ability to appeal, innovative firms may face generic competition even while their drugs are still under patent protection. Greater predictability would reduce the risk and uncertainty surrounding investment in pharmaceutical research and development, undeniably making such investments more attractive. Moreover, as Scoffield notes, even generic manufactures see the potential for benefits to the process of legal appeals: "the generic drug industry is willing to entertain a change in the avenues for legal appeals, if it means making a more coherent system for an industry known for its litigious nature" (Scoffield, 2012: 2).

The associated benefits from reform in this litigious industry are tremendous. The "pharmaceutical space is where all the big patent litigation is happening in Canada right now. $22.3 billion is spent annually by Canadians on prescription drugs, of which 58% are patented. The developing case law in this area is therefore very lucrative and high-stakes. This year, about 64% of all Canadian patent litigation will be dedicated to pharmaceuticals alone" (Innovation Law blog, 2012: 1). The pharmaceutical industry is the most litigious industry in Canada; additional clarity and coherence in the legal landscape could greatly reduce the number of lawsuits and their corresponding costs. Specifically, reduced uncertainty surrounding patentability standards and greater predictability in the legal arena would benefit all parties.

Finally, in light of the debate around protection for the innovative pharmaceutical industry, it is important to recognize that patent policy isn't medical innovation policy. Patents and the supporting IP regime are but one way to promote innovation. Admittedly, many alternatives exist, each with their own limitations and weaknesses. Importantly, patents are valuable and widely used because they link innovation to market-based incentives. The success of this structure in promoting innovation and generating growth have led to the global adoption of patents as the primary means of protecting pharmaceutical innovation. The future promise of stronger IP protection and an enhanced intellectual property rights regime necessitate the adoption of the proposed changes to Canadian IP law.

Conclusions

Historically, international trade agreements have acted as catalysts for Canada to re-envision the intellectual property protection available to the innovative pharmaceutical sector. Important precedents were set with Canada's accession to the North American Free Trade Agreement in 1993 and again in 1995 with the Marrakesh Agreement, which established the World Trade Organization. These

agreements led to important changes to Canadian patent law and signaled strong support for a vital domestic innovation-based pharmaceutical industry. It comes as no surprise that the current negotiations surrounding the CETA and TPP agreements also include discussions around how to reframe intellectual property protection in the pharmaceutical sector.

Current negotiations focus on changing three aspects of the Canadian IP regime in order to provide stronger intellectual property rights protection to the innovative pharmaceutical industry. In particular, Canada should enhance and extend the data protection regulations to ten years of protection (with a maximum of eleven years) and include new indications. In addition, Canada should enact 12 years of protection for biologics. Second, innovative pharmaceutical firms should be eligible for patent term extensions in order to recover time lost due to mandatory governmental regulatory and marketing approvals. Lastly, Canada should bolster the legal rights of innovative firms to appeal unfavourable patent decisions. The adoption of the innovator's right of appeal would level the playing field, allowing both innovator and generic firms the right of appeal if the court rules against them. If adopted, these changes would bring the Canadian regime in line with international standards.

The proposed changes would strengthen IP protection for the research-based pharmaceutical industry in Canada, encouraging innovation and the stream of benefits that flow from this sector. A multitude of studies have shown that knowledge-based industries are the engines of economic growth. Competition among countries for these industries is fierce and increasingly global. As the Canadian Intellectual Property Council stated 2011, "[i]f Canada wants to keep attracting investment and high paying jobs, some work still needs to be done to achieve the same kind of IPR protection that other jurisdictions, such as the United States and the European Union, offer" (CIPC, 2011: 10).

The benefits stemming from international trade agreements and support of innovation-based industries are numerous. From a wider perspective, the benefits will include increased trade and greater access to foreign markets, the growth of IP-intensive industries, and the concurrent benefits to economic growth. Further benefits include reduced legal ambiguity and litigation, additional job creation in the pharmaceutical industry, greater pharmaceutical self-sufficiency, and additional innovation in cutting-edge treatments and therapies. At first glance, the advantages to stronger intellectual property protection for the innovative pharmaceutical industry are impressive. Closer scrutiny reveals them to be essential for Canada's continued economic growth and prosperity.

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Canada's Trade Agreements and the Pharmaceutical Industry: The Road to Asia Runs Through Brussels

by Laura Dawson[9]

Summary

In international trade negotiations Canada has both an offensive interest in providing strong intellectual property (IP) protection to promote investment in the research-based and biotechnology sectors and defensive interests to hold the line on drug prices and accessibility. As an advanced economy seeking to expand its market share in the global knowledge economy, Canada's IP regime is relatively strong when compared to China and India, but is relatively weaker than either the United States or the European Union. Thus, in bilateral negotiations with these IP powerhouses, Canada tends to face reformist pressures but, when developing countries are added to the mix, such as in the Trans-Pacific Partnership (TPP), Canada may be among the countries in favour of stronger IP protection on certain issues.

Domestic overview

The Canadian pharmaceutical sector comprises a research-based pharmaceutical industry made up mostly of multinational transplants, a generic industry that includes both domestic and multinational firms, and a nascent biopharmaceutical[10] sector that includes a number of small domestic enterprises. Canada's total phar-

9 The author wishes to acknowledge Stefania Bartucci and Yamily Camacho who contributed to this paper. She also thanks Stephen Easton and other anonymous reviewers for their comments and suggestions. Any remaining errors rest with the author.

10 Traditional pharmaceutical products are made by combining specific chemical ingredients in an ordered process. Biopharmaceutical products ("biologics") are derived from life forms often using recombinant DNA technology. See Biotechnology Industry Association, 2010.

maceutical production was valued at $10 billion in 2011 and the sector has grown by more than 6 percent annually since 2006. Over the past 10 years, pharmaceutical employment has increased by 14 percent.[11]

The manufacturing portion of the sector employs nearly 30,000 people, mostly clustered around Toronto and Montreal. Research-based pharmaceutical products account for 76 percent of Canadian sales and 40 percent of prescriptions while generics make up the balance.

With only a 2.6 percent market share, Canada is not a big player in the global pharmaceutical market. About half of Canadian production is exported, mostly to United States, while about 85 percent of the drugs consumed in Canada are imports, either from the United States or the European Union.

Aging populations in OECD countries and a rising middle class in the developing world suggest a strong potential for pharmaceutical growth, but Canada's comparative advantage is not immediately clear. Countries like Ireland, Denmark, Switzerland, and the UK export far more than Canada does (CBOC, 2013). Moreover, the major economic benefits of the sector accrue to the patent holders. Ten companies control one-third of the trillion dollar global pharmaceutical market (IMS, 2010). Six are based in the United States and four in Europe (WHO, 2013). Canada's generic producers, meanwhile, have established a strong niche providing quality products for mostly domestic consumption, but it is unlikely that they can compete against generic giants from India and China for significant global market share.

The consulting firm PWC predicts that India and China will dominate global generic production and exports by 2020 (PWC, 2012). More than 80 percent of pharmaceutical consumers live in the developing world. Moreover, inputs are inexpensive. India and China together produce more than 80 percent of the active ingredients of all drugs used in the United States (Harris and Thomas, 2013). India has achieved top global spot as a generic manufacturer through weak or limited enforcement of patent rights. By contrast, China's more assiduous attention to patent protection is encouraging brand-name manufacturers to form joint ventures in China in order to manufacture generic versions of their own products when their patents expire (Want China Times, 2012).

This leaves Canada's small biopharmaceutical sector as a wild-card prospect for future export growth. But it will not be easy for domestic biotechnology to build a competitive global position. Canada's domestic market is small, competition is stiff, and development costs have increased tenfold over the past three decades to an estimated average of $1.8 billion for each new drug (Jack, 2012).

The 1994 WTO agreements include the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which modernized and consolidated multinational regulation of intellectual property including patent protection for

11 Unless otherwise indicated, statistics in this section are from Industry Canada (2012).

pharmaceuticals. With TRIPS as a benchmark, Canada is now engaged in a number of free trade negotiations, of which the Comprehensive Economic and Trade Agreement (CETA) with the European Union and the Trans-Pacific Partnership (TPP) are the most important by market size. Both agreements include demands for TRIPS-plus provisions that, if accepted, will require reforms to the Canadian regulatory regime. At the same time, both of these agreements provide market access opportunities that may justify concessions by Canada.

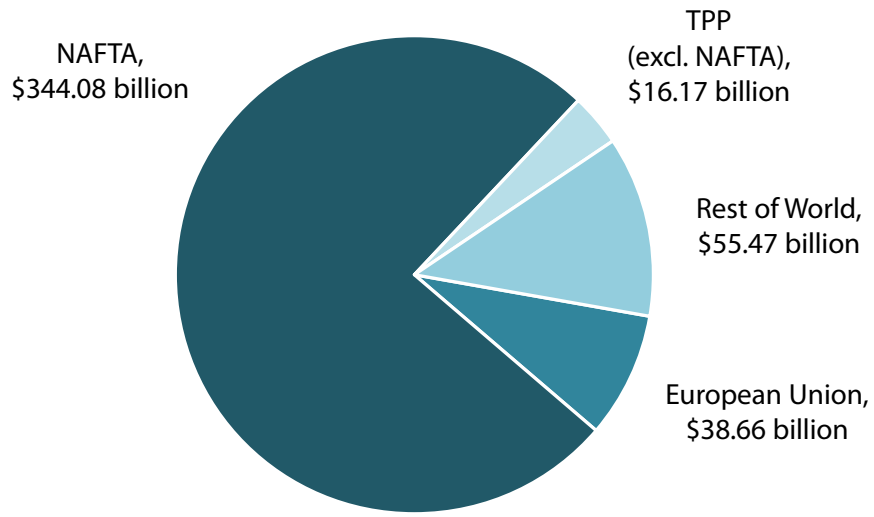
CETA market opportunities

The European Union is the world's largest single common market comprising 27 member states, a total population of over 500 million, and a GDP of $17.4 trillion. Although trade with the US through NAFTA still dominates Canada's trading activity, the EU is Canada's second-largest export market (see figure 1) (DFAIT, 2013).

According to a joint study by the Canadian and EU governments, the CETA could provide a 20 percent boost in Canada's exports to the EU, generating more than $11 billion annually (DFAIT, 2013). These figures represent gains derived from the elimination of tariffs, the liberalization of trade in services, and the reduction of costs related to non-tariff barriers.

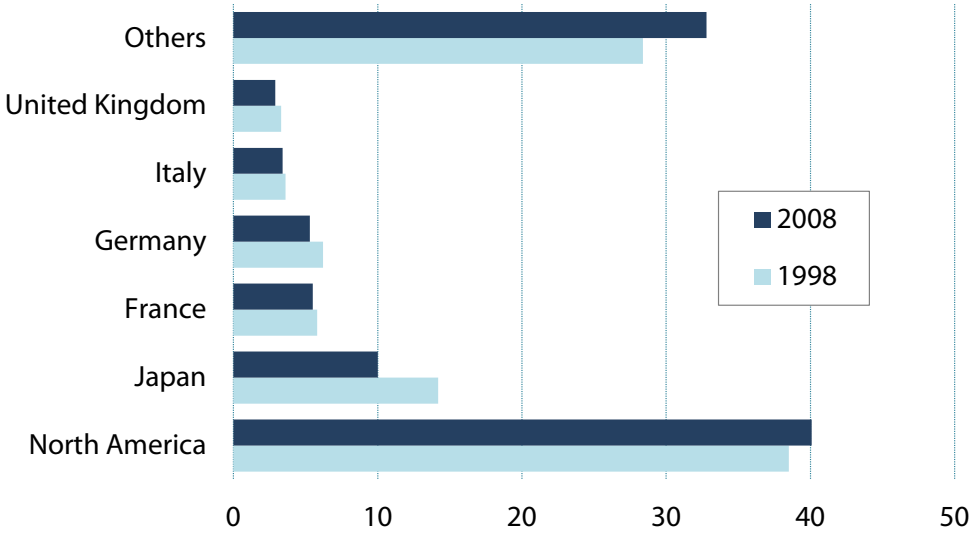
Canadians exported $55.3 billion in goods and services to the EU in 2011 and two-way investment flows reached nearly $350 billion (Canadian Trade Commissioner Service, 2012). Although most goods traded with the EU already

Figure 1: Canada Export Market Share (2012, CA$ billions)



Source: Industry Canada, Trade Data Online.

Figure 2: Change of Pharmaceutical Production Market Share (%)



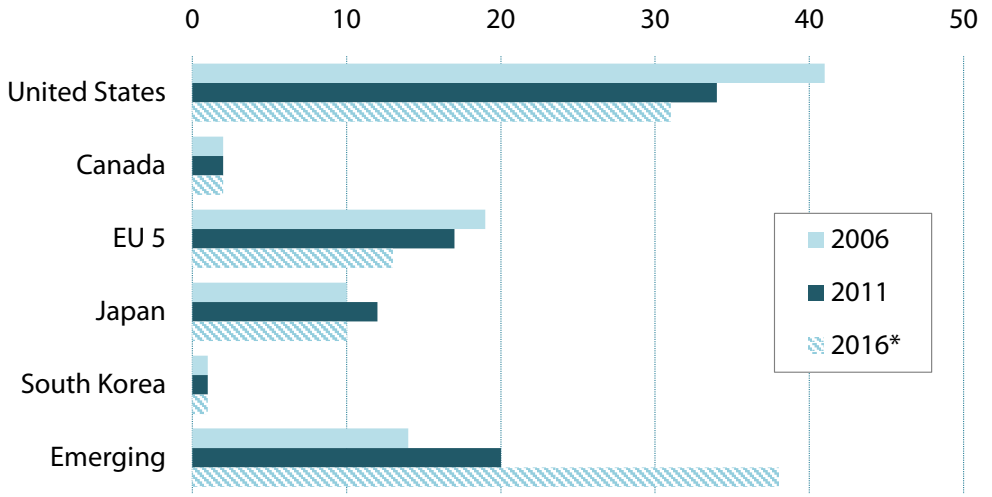
Source: IMS Health (2010), *IMS World Review at Implementation of Patient Oriented Health Care.*

enjoy tariffs of less than 3 percent, Canadian exports of fish and seafood, footwear, and textiles encounter tariffs in excess of 20 percent (DFAIT, 2013). Other prospective gains include access to the European Union's $3 trillion government procurement market and liberalization of services exports (European Commission, 2012). A further $2.3 billion in benefits could be realized through reduction of non-tariff barriers such as regulatory duplication, and packaging and labelling requirements (European Commission, 2012).

In the pharmaceutical industry, the EU is a global powerhouse. The sector is characterized by a relatively small number of very large, capital-intensive enterprises with production valued at some US$110 billion in 2010 (Eurostat, 2013). However, with increased competition from emerging market producers, the EU's relative market share is declining (see figure 2).

In stark contrast to the rapid growth rate of emerging market demand, EU demand for pharmaceuticals is shrinking (see figure 3). IMS Pharma predicts an average annual growth rate of 15 percent a year for developing markets and only about 5 percent for developed countries through 2014 (IMS, 2010). Nevertheless, as a relatively large, stable, and prosperous global market, the EU offers Canada an opportunity to diversify and reduce its reliance on the US market.

Figure 3: Global Spending on Pharmaceutical Products (US$ billions)



* = Projected;
"EU 5" includes France, Germany Italy, UK and Spain;
"Emerging" includes China, Brazil, India, Russia, Mexico, Turkey, Poland, Venezuela, Argentina, Indonesia, South Africa, Thailand, Romania, Egypt, Ukraine, Pakistan and Vietnam.

CETA negotiating dynamics

Canada and the EU have been negotiating a Comprehensive Economic and Trade Agreement (CETA) since 2009 and a conclusion is expected in 2013.[12] In the pharmaceutical negotiations, the European Union has said that it is seeking to remedy "deficiencies" in the Canadian system (Commission of the European Communities, 2009). For Canadian negotiators, the questions they have been facing are how much are they willing to change, and what would be the benefit?

Market exclusivity—One of the non-contentious issues in the CETA is the duration of patent protection, since the WTO TRIPS agreement helped to harmonize the patent terms among member states.[13] TRIPS Article 33 requires a term of patent protection for not less than 20 years from filing date. Canada's *Patent Act* pro-

12 Information about the content of ongoing negotiations is highly speculative. Statements in this briefing about CETA and TPP pharmaceutical offers and requests are drawn from leaked texts, public documents, and government briefings.

13 All CETA and TPP states are also WTO members.

vides 20 years of market exclusivity for pharmaceutical products that are novel, useful, and non-obvious. It is common for a single drug to encompass many technologies and be protected by many patents with distinct expiry dates (Crowley and Lybecker, 2012).

Patent term restoration—Patent term restoration is remedial time that can be added at the end of a company's patent life to help compensate for clinical development time and the time required to obtain approval from regulatory authorities.[14] Canada does not currently provide patent term restoration and is the only country in the G7 that does not. The EU and US both offer terms of up to five years, depending upon the length of the clinical and regulatory delays. *The EU is asking Canada for patent term restoration of up to five years.*

Patent linkage—Patent linkage refers to systems in which the regulatory approval of a generic drug cannot take place until the innovator's applicable patent has expired, been invalidated, or the patent holder provides consent.
In the United States, the Food and Drug Administration (FDA) maintains a list of pharmaceutical patents and approved uses in what is colloquially known as the "Orange Book," and will not provide marketing approval for a generic copy of innovative products that would infringe a patent listed in the Orange Book.

The EU does not have a formal patent linkage mechanism but, when a generic launches a drug before the expiry of a patent, the innovator may sue for infringement and also apply for an interlocutory injunction that preserves the status quo and prevents the generic from launching until litigation is complete or the parties have settled (IPIC, 2012).

Similar to the US, Canada's linkage proceedings are governed by the Patented Medicines (Notice of Compliance) Regulations (PM(NOC)). Under these regulations, Health Canada will not provide regulatory approval for a generic drug until the patent is invalidated or unless a patent holder consents. The regulations provide for a period of up to a maximum of 24 months for an expedited judicial process with respect to the patent's invalidity, and during this process the generic drug may not be introduced to the market.

Right of appeal (patent linkage)—In theory, either the innovator or the generic can appeal a PM(NOC) finding, but in practice, the Canadian Federal Court of Appeal (FCA) will not hear appeals from innovators because they are deemed to be moot under the regulations. In contrast, generics do have an effective right

14 In Canada, a product must be reviewed by various regulatory authorities before it can be listed on a public formulary. Health Canada is the federal safety regulator of pharmaceuticals; a federal/provincial/territorial body known as the Canadian Agency for Drugs and Technologies in Health makes recommendations with respect to product safety and efficacy; and the provincial/territorial governments make the ultimate decisions regarding product listings.

Table 1: Major Dynamics of the CETA Pharmaceutical Negotiations

	Canada	EU
Patent Term Restoration		
Current	None	Up to 5 years; as long as total patent term does not exceed 15 years.
Proposed	EU is asking Canada for up to 5 years of patent term restoration.	
Right of Appeal on Patent Term Linkage		
Current	No	Yes; for equivalent system
Proposed	EU is asking Canada for fair and equitable treatment of generics and patent holders where patent linkage mechanisms exist, including regarding their respective rights of appeal.	
Data Exclusivity		
Current	Maximum term is 6 + 2 + 0.5 = 8.5 years: ◭ No submission from generic manufacturer for 6 years ◭ No regulatory approval of a generic equivalent for an additional 2 years ◭ An additional 6 months is granted for submissions related to paediatric studies	Maximum term is 8 + 2 + 1 = 11 years: ◭ No submission from generic manufacturer for 8 years ◭ No regulatory approval of a generic equivalent for an additional 2 years ◭ An additional 1 year data exclusivity for a new indication
Proposed	EU is asking Canada to extend data exclusivity terms to EU standards	

of appeal to the FCA.[15] *The EU is requesting an equivalent innovator's right of appeal.*

Data exclusivity—When an innovator is seeking regulatory approval for a new innovative drug, the company is required to submit the results of their clinical testing data to Health Canada to verify the product's safety. Generic drug companies wishing to market copies of the original product would incur significant costs if they had to conduct their own tests instead of relying upon the innovator's clinical testing data when making their own applications to regulatory authorities.

Under Canada's current regime, generic companies cannot rely upon the innovator's testing data for product approval for a cumulative period of eight years (plus a possible additional six months for paediatric studies). The EU offers a base

15 The innovative company may, however, sue for patent infringement, but innovators have argued that this remedy is ineffective because it is costly, time consuming, and does not prevent the generic from taking over the innovator's product market in the meantime.

data exclusivity period of 10 years (plus a possible additional year for new indications) (see table 1). *The EU is asking Canada to extend its terms of data exclusivity to harmonize with the EU system.*

Discussion

Canada's negotiating position in the CETA has been shaped by two distinct and potentially contradictory messages from stakeholders. The research-based and biotechnology companies see reforms as a way to stimulate investment and innovation (Pharma Letter, 2011). The generic industry is wary of proposals that would restrict competition from generic drugs and possibly raise prices (CGPA, 2012). The CETA is a unique trade negotiation because it includes the direct participation of the provinces in areas falling within their constitutional jurisdiction, such as health care.[16] This could tip the scales towards outcomes favouring the generic industry because of provincial concerns about potential increases to drug costs. However, it should be noted that intellectual property, including patent-related issues, are an exclusively federal area of constitutional jurisdiction and, as such, are being negotiated directly between the EU and Canada without provincial participation.

At the same time, Canada lags behind both the European Union and the United States in such areas as patent term restoration, a patent linkage right of appeal, and data exclusivity. As Canada continues to participate in negotiating fora where these more powerful states dominate, it will face continued pressure to reform its policies or offer concessions in other areas to maintain policy independence. The question then becomes whether or not the costs of policy sovereignty outweigh the benefits, taking into account the economic benefits of the trade agreement as a whole.

Trans-Pacific Partnership market opportunities

The 12 Trans-Pacific Partnership negotiating parties are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam. The TPP countries represent a prospective free trade zone of over 785 million people with a GDP in excess of $26.4 trillion. For Canada, the TPP would not only deepen existing agreements with Chile, Peru, Colombia, Mexico, and the United States, but would also open the doors for liberalized trade with the Asian countries where Canada's market share is relatively small (Chen, 2013). Petri and Plummer (2012) estimate that the TPP could yield annual income gains of $9.9 billion for Canada and increase the country's exports by some $15.7 billion.

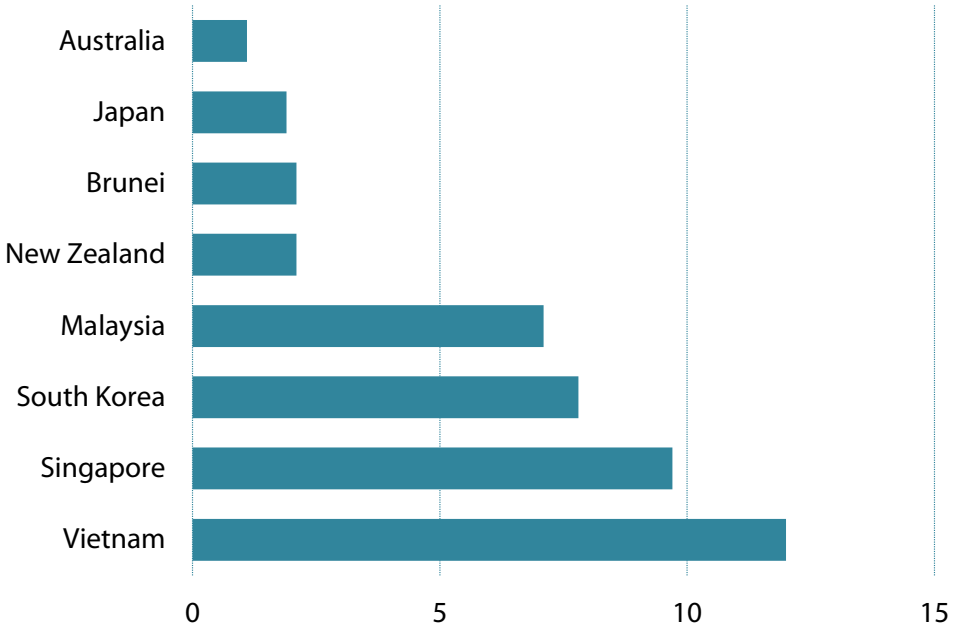
16 Trade agreements are traditionally negotiated by Canadian federal negotiators with authority delegated by the provinces in areas of provincial jurisdiction in exchange for ongoing consultation.

In addition to defensive interests to ensure that current NAFTA benefits are not eroded by the future TPP (Dawson, 2012), this new agreement would also provide Canada with direct benefits in such areas as goods and services in the extractive, transportation, and agricultural sectors (Chen, 2013). Canadian banks and insurance companies could benefit from rationalized rules on state-owned enterprises (Hoffman and Torobin, 2012).

The TPP provides Canada with its first major free trade agreement in the Asia Pacific region and strengthened ties with Latin America. However, the short-term economic benefits of the Trans-Pacific Partnership are relatively small. Canada already has free trade agreements with five of the TPP members and negotiations were recently launched with Japan. Also, in trade negotiations, the smaller and less developed economies do relatively better in terms of market access gains than larger or more advanced economies (Petri, 2012).

The major attractions of the TPP are the size and dynamism of the Asian market. The emerging economies in the TPP have growth rates that are roughly double those of our traditional trading partners in the United States and Western Europe. The APEC countries, of which the TPP members are a subset, account for 44 percent of world trade and 55 percent of global GDP (USTR, no date). As emerging market consumers become relatively better off, their demand for consumer and luxury goods, including pharmaceuticals, increases (see figure 4).

Figure 4: Annual Average Growth Rate of Per Capita Pharmaceutical Expenditure, Asian Trans-Pacific Partnership Parties, 2000-2009 (%)



Source: OECD/WHO (2012): 75.

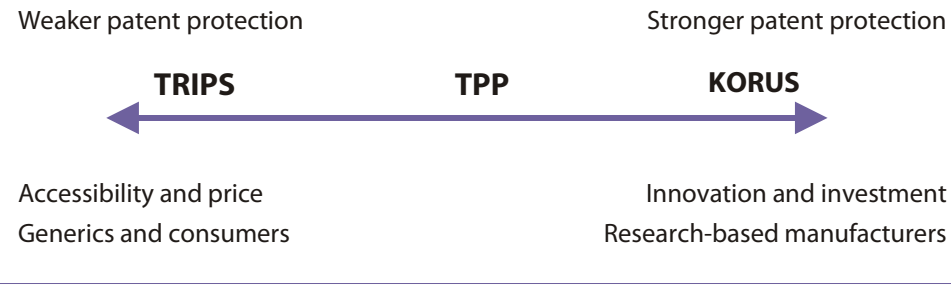
In addition to offensive interests in market share, Canada also has defensive interests. The United States and European Union are aggressively pursuing free trade agreements in Asia and Latin America, and Canada must maintain a presence in order to avoid being shut out of preferential market access arrangements.

TPP negotiating dynamics

The major protagonist for change in the Trans-Pacific Partnership negotiations is the United States. It is seeking strong IP protection that meets or exceeds that in its recent bilateral free trade agreements. The US agreement with South Korea (KORUS), is considered to be the gold standard (Silverman, 2011). It moves beyond the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) to provide mandatory patent linkage, patent term restoration, and data exclusivity. The Australia-US Free Trade Agreement is similar, so Australia can be expected to support the United States on KORUS-like measures (Schott et al., 2013).

Some developing country members (most of whom are drug consumers, not manufacturers) will be pushing towards a TRIPS-based agreement that requires little or no departure from their existing WTO commitments and supports an agenda of accessibility to lower-priced generic drugs.

Figure 5: Continuum of Pharmaceutical Patent Protection



As figure 5 illustrates, the positioning of the TPP agreement relative to TRIPS and KORUS will depend on the ability of each side to move the final text toward or away from strong IP protection. Developing countries will resist change unless trade-offs are offered in other areas of interest.[17]

17 At the time of writing, the TPP partners were exchanging information on their domestic systems of pharmaceutical protection, but had not yet started text-based negotiations.

Japanese game-changer

Japan is a relatively recent entrant to the TPP negotiations. It is a valuable market for TPP exporters because of its high demand for imported foreign drugs. Prime Minister Shinzo Abe has also identified support for the development of the country's nascent research-based pharmaceutical manufacturers. Thus, Japan's continued support for strong patent protection is very likely.

While the mechanisms are not identical, Japan's effective level of patent protection is acknowledged to be at or above that of the US.[18] For example, Japan does not have a directly equivalent data exclusivity system, but its current law prevents generic companies from applying for regulatory approval until the brand-name drug has been on the market for the equivalent of eight years, with potentially up to four additional years for new indications, far in excess of the US TPP proposal for five-year exclusivity (Finston Consulting, 2011). Japan's patent term restoration system is also roughly equivalent in terms of remedial assistance for delays to the system in the United States. With the entry of Japan to the negotiations, the United States has a potential ally, with considerable market heft, for its reformist proposals.

Access window

In 2011, the US presented a White Paper on Trade Enhancing Access to Medicines (TEAM) that seeks to establish a balance between strong IP protection and access to medicines, especially in developing countries (USTR, 2011a). Central to the TEAM proposal is the concept of an "access window," which would provide pharmaceutical companies with stronger IP protection in exchange for their commitment to seek marketing approval in TPP countries as quickly as possible. The Office of the United States Trade Representative (USTR) claims that this will expedite the availability of lifesaving medicines in TPP markets and also speed up access for generics to enter those markets (USTR, 2011b).

The access window proposal has reportedly faced skepticism from US companies and strong resistance from TPP partners (Inside US Trade, 2013a; Inside US Trade, 2011).

Pricing

National regimes for drug pricing are also under scrutiny in the TPP. The United States has proposed a transparency chapter that would require countries with national drug pricing and reimbursement programs (such as Canada, Japan, and New Zealand) to establish a system of best practices covering such issues as decision-making processes, use of information, and appeal of pricing decisions.

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18 Author's interview with specialist in Japanese pharmaceutical regulatory specialist, Paul King of King PLLC (www.kingpllc.com), on December 13, 2012.

The US insistence on enhanced transparency standards is believed to be targeted at the pricing and decision making procedures of New Zealand's Pharmaceutical Management Agency (PHARMAC) (Inside US Trade, 2013b).

Scope of patentability/ Exclusions from patentability

The United States is proposing to expand the scope of patentability by requiring countries to permit patent applications on modifications or variations of existing medicines. Critics charge that such measures will prevent the timely introduction of generic equivalents (Doctors Without Borders, 2013). Innovators maintain that such changes legitimately protect incremental innovations to existing medicines that provide important therapeutic benefits for patients (such as time-release dosages) and ultimately improve health outcomes (IFPMA, 2013).

The US is also seeking to limit possible exclusions from patentability. Under the TRIPS agreement, countries are permitted to make a broad range of exclusions from patentability including for plants, animals, and diagnostic, therapeutic, and surgical methods (Flynn et al., 2012). The US TPP proposal narrows the scope of exclusions to those that are necessary to protect public order or morality, or human, animal, or plant life or health.

Patent term restoration—The United States is seeking patent term restoration from all TPP countries.

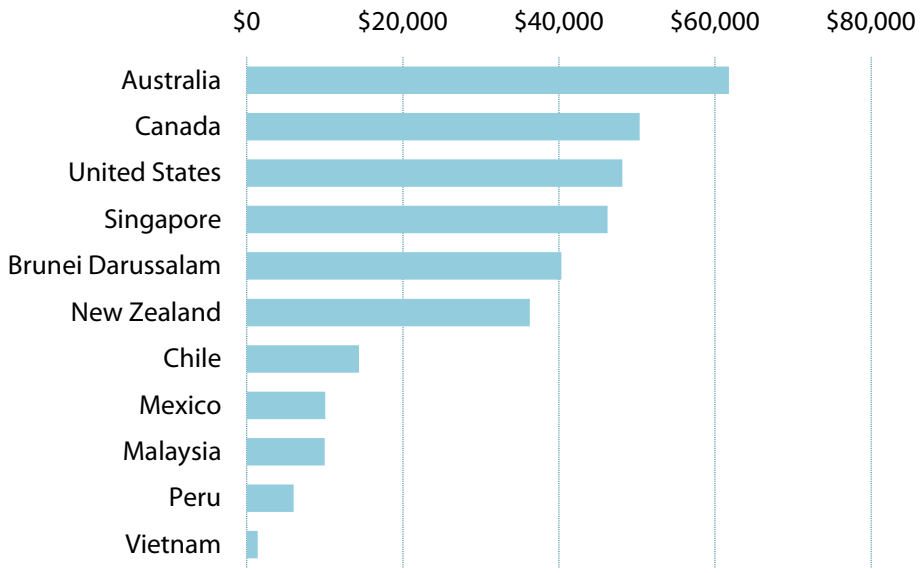
Patent linkage—The United States is proposing is that all TPP countries adopt patent linkage. The alternative, which occurs in many developing countries, is for health authorities to grant marketing approval to generics without verifying the status of the innovators' patents.

Data exclusivity—The US proposal is roughly based on KORUS, the US agreement with South Korea, and calls for data exclusivity for an as-yet indeterminate period.

Although other countries have not distinguished between biological and chemical drugs, the US treated them as a special class in the 2010 *Affordable Care Act,* which provides 12 years of data exclusivity for biologics. However, in annual budgets, the Obama White House has proposed scaling back data exclusivity for biologics to seven years in order bring generics to market faster and save on Medicare and Medicaid costs (Palmer, 2012). It remains unclear at the time of writing whether or not the US will be asking its TPP partners for an extended data protection term for biologics equivalent to that required under its domestic legislation.

Until the US takes a formal position on whether or not they want an extended period for biologics, the other TPP parties will remain noncommittal.

Figure 6: GDP per capita of Trans-Pacific Partnership Parties (2011, Current US$)



Source: World Bank, 2011.

Special and differential treatment—While it has not yet evolved into an official position, there are indications that the US might support a system of special and differential treatment for lower-income developing countries, similar to the flexibilities that it offered in its bilateral trade agreements with Panama, Colombia, and Peru. These provisions could include longer phase-in periods, shorter periods of data exclusivity, voluntary patent term linkage, and patent term restoration.[19]

Special and differential treatment would require a definition of "developing country" to be included in the agreement (Inside US Trade, 2013b). Although the benefits would presumably apply to lower-income countries like Peru and Vietnam, higher-income developing countries such as Chile, Malaysia, and Mexico are likely to object if they are left out of the tent (see figure 6).

Comment

The US is seeking to promote access and affordability through the Trade Enhancing Access to Medicines and through special and differential treatment proposals,

19 The provisions of the so-called May 10 Agreement are discussed in Ferguson et al., 2013.

Table 2: Major Dynamics of the TPP Pharmaceutical Negotiations

US Proposal	Possible allies	Possible opponents
Access Window—companies are rewarded with stronger protection if they seek marketing approval swiftly in TPP countries		Many
Pricing Transparency		New Zealand, Canada, Japan
Special and Differential Treatment	Vietnam, Peru, Brunei; other low-income developing countries	Chile, Singapore, Mexico, Malaysia; other higher-income developing countries
Scope of Patentability—increase scope and decrease exclusions		Many
Patent Term Restoration	Japan Australia	Canada (if not in CETA); Developing countries
Patent Linkage	Canada, Australia	Developing countries
Data Exclusivity	Depends on term	

but it is also promoting innovation through extended data exclusivity for biologics, patent term restoration, and a narrowed band of patentability exclusions. If and when the US position becomes better defined, Canada and other TPP partners will be able to determine where they will support US interests and where they will oppose them (see table 2).

Industry insiders suggest that because of developing country considerations, the final TPP agreement will resemble KORUS, but will not go as far in terms of IP as the CETA or the prospective US-EU free trade agreement.[20] At the same time, US negotiators will try to move the developing countries as far as possible from the TRIPS; the ultimate goal is to establish the Trans-Pacific Partnership as the standard-bearer for the region and reduce the influence of China and India on trade rules and their implementation (Gordon and West, 2011).

Although Canada has faced pressure from the United States over the past decade to tighten up its IP regime, especially in the area of copyright enforcement, there should be relatively little pressure for further reforms at the TPP table, especially if Canada adopts patent term restoration, extended data exclusivity, and

20 Author's confidential interviews with US pharmaceutical representatives in Washington, DC, in September and October, 2012.

right of appeal of for brand-name drug manufacturers in the CETA. In a post-CETA environment, Canada may consider using support for US TPP pharmaceutical positions as leverage for progress in other areas of importance to Canada.

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